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09/478,598	01/06/2000	A. Gururaj Rao	5718-16A	1892

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ALSTON & BIRD LLP  
PIONEER HI-BRED INTERNATIONAL, INC.  
BANK OF AMERICA PLAZA  
101 SOUTH TYRON STREET, SUITE 4000  
CHARLOTTE, NC 28280-4000

[REDACTED] EXAMINER

TUNG, PETER P

ART UNIT	PAPER NUMBER
1652	10

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/478,598</b>	Applicant(s) <b>Rao et al.</b>
Examiner <b>Peter Tung</b>	Art Unit <b>1652</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Oct 19, 2001.

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 54-118 is/are pending in the application.

4a) Of the above, claim(s) 84-96 and 108-114 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 54-83, 97-107, and 115-118 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15)  Notice of References Cited (PTO-892) 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 19)  Notice of Informal Patent Application (PTO-152)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

1. Claims 54-118 are pending.
2. Claims 84-96 and 108-114 are withdrawn from further consideration as being drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 54-83, 97-107 and 115-118 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is explained in the previous Office action.
5. Applicants argue that the Examiner's comments with regard to antibodies are not applicable to oligomerizing or dimerizing proteins. Applicants argue that the prior art teaches the use of antibodies in many instance to discern between completely folded proteins having their native conformation and proteins which are only partially folded. Applicants argue that the prior art teaches that identification of antibodies suitable for conformational probes involves an amount of work considered in the art to be routine. The prior art teaches the production of antibodies suitable for conformational probes and procedures for determining stoichiometry of antibody

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binding and for measuring affinity of binding. Applicants argue that the important consideration in determining whether experimentation is undue or appropriate is what those in the art consider routine and that it has been recognized that immunologically based experiments can require more work than experiments in other areas.

6. Applicant's arguments filed 10/19/01 have been fully considered but they are not persuasive. With regard to the rejection based upon antibodies as applied to dimerizing or oligomerizing proteins, the instant claims do not limit what a dimerizing protein is. As such, an antibody binding to a protein and antibodies in general are dimerizing or oligomerizing proteins. While the prior art may teach the use of antibodies to discern between completely folded proteins from an identical protein which is not folded to the native conformation, every protein has a different structural characteristic such that using antibodies to screen for conformational changes for any protein would not necessarily be routine. The instant invention screens for conformational changes arising from changes made to the primary structure of the protein. The prior art of record only teaches the use of conformational antibody probes where the protein has an unmodified primary structure and where differences in the protein's conformation are due to its state of folding. This is different from how conformational antibody probes would be used in the instant invention, where changes are made in the amino acid sequence of a protein. Although immunologically based experiments may or may not require more work than experiments in other areas of endeavor, the instant claims encompass using immunologically based experiments in the assessment of a protein's native conformation, an area of work which is not routine and would

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require undue experimentation. Additionally, it is not clear in the instant application that Applicants have been able to make changes to the primary structure of the disclosed VSP $\beta$  and determine the proteins conformation by the use of conformation-sensitive antibody probes.

*Conclusion*

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



PONNATHAPU ACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600